# Design and modeling of a few innovative life-saving devices for pre-hospital trauma care

*A Synopsis of the proposed work to be carried out in pursuance of the requirement for the award of the degree*

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# I. INTRODUCTION

It is reported extensively in the literature that in traumatic injuries, the concept of „golden hour" medical management is all important. Such traumatic injuries can result from rail or road accidents, natural disasters or warfare. People who survive the first hour after the injury have more than 95% chance of survival on reaching hospital. More recently, the concept of „medical management" in the first 15 minutes is gaining acceptance. Hence medical aid in the first 15 to 60 minutes becomes crucial to save lives.

A number of emergency drugs are now available and are very effective. Focus now needs to be on life saving devices and technologies in the pre-hospital environment as this has been a neglected area. Most of the biomedical devices and technologies presently are sophisticated and hospital based. Since the place of such accident and disasters cannot be predicted, it is essential to spread such life saving devices / technologies far and wide. Thus these technologies have to be very cost effective and simple and safe enough to be handled by semiskilled personnel. Engineering establishments, strategists and innovators need to come together to design and model such simple cost effective innovative devices and technologies that can be used on large scale, preferably at the site of accident or disaster or in the ambulance to save precious lives.

The aim of this work is to design and model a few cost effective life saving devices for pre-hospital trauma care based on scientific and technical principles. The output will be used for prototyping and industrial production of the devices.

After survey, it was realized that there are two broad areas where new devices can be designed that can further reduce the mortality and morbidity in the Golden hour. These broad areas are a) stopping the arterial bleeding and supporting the wounded tissue, b) supporting equipment in the ambulance.

To the best of our knowledge, the devices as described below are not available and need to be made available for testing after designing, modeling and making prototype.

# II. OBJECTIVES
# (DEVICES / TECHNOLOGIES TO BE DESIGNED & MODELLED)

## *1. Pneumatic tourniquet & limb scaffold*

*Need:* The current technology to stop bleeding and support mutilated limb is more than 50 years old and requires the help of another person. It consists of using expandable rubber tubes like foley"s catheter to tie and choke the major artery supplying the upper or lower limb to stop bleeding and wooden plastic or steel rods with simple dressing material to provide support mutilated limbs during transport. Even this is not available in kit form and there may not be time

and expertise to use local material to make such scaffolding. The safety and efficacy are suboptimal because the force to tie the tube can be excessive causing local tissue damage causing ischemia downstream. Also, the tube and scaffolding are likely to get loose and thus becoming useless. Obviously it cannot be used on thorax and abdominal wounds.

*Rational & work plan:* It is envisioned to upgrade this makeshift but widely use technique by a safer and more effective device. We plan to design an inflatable textile tourniquet and scaffold based on pneumatic principles that will provide more safety, better controlled and changeable pressure, leverage and the advantage of shelf use. We plan to design such a biomedical device based on physical and physiological principles and make specifications prior to industrial prototyping.

*Specifications:* A robust tourniquet will be designed with long reusability, light and strong, washable, tourniquet has 140 mm Hg maximum pressure and sustainable pressure for at least 10-20 min and scaffold has maximum pressure 100 mm Hg and sustainable pressure for at least 120 min. Usable on upper limb and thigh.

*2. Cooling paraphernalia for reducing demand of oxygen in brain and body*

*Need:* In deserts and boiler rooms of ships, professionals are exposed to $50^{o}$ C plus environment for prolonged periods. Not only this reduces the efficiency of the personnel (working shifts may be reduced to 2-3 hrs instead of usual 8 hrs) and make working extremely uncomfortable, life-threatening conditions such as hyper acute dehydration and renal failure or heat stroke may be precipitated. When a person losses blood and slips into coma due to lack of oxygen in blood, there is a need for devices in ambulance that can prolong life to the extent that the patient can be safely delivered to the hospital for specialized care. There is a need to have innovative clothing that cools the body and is easy to wear at work place which is cost effective & comfortable.

*Rationale & work plan:* Several innovations such as light reflective dressing, fan with circulating air, compressor with circulation cod liquid etc have been made. It is known that hypothermia reduces the need of oxygen in the body and brain to prolong life. However, hypothermia below a limit can kill rather than saving. Therefore the application of the technology is limited to ICUs (Intensive-care unit) in hospital where sophisticated equipment is used. We plan to design and then develop simple cooling devices that can safely be used in ambulances to lower the central body temperature to some extent and insulating light dressing with inner lining /pockets of PEG (Polyethylene glycol) as heat dual-phase exchanger. The design will be based on physical principles and practicality. Specifications will be developed theoretically and through modeling.

*Specifications:* Cooling paraphernalia will be designed with a safe chemical for 8-10 hours transport and reuse capability. The PEG (Polyethylene glycol) has low toxicity, flexible, water soluble and heat dual-phase exchanger. The physical parameters need to be defined.

*3. Multiportal oxygen delivery & air suction catheter*

*Need:* Normally, one catheter and oxygen cylinder/suction machine is available per patient in

emergency ward and ambulance. However, in times of major disasters, a number of patients have to be given oxygen and suctioned to clear blood/debris from a single source. For this, oxygen delivering multiportal and suction multiportal catheter can be used for lifesaving. Such devices are presently unavailable.

*Rationale & work plan:* We plan to design such a simple device with a single input portal for receiving oxygen and having multiple output portals with separate mask and control system. We also plan to design a simple device with multiple input portals for receiving debris from the mouth and having single input portal for discharging the waste. Separate disposable receivers and control system will be required for each portal. The design will be based on physical principles and practicality. Specifications will be developed theoretically and through modeling.

*Specifications:* A multiportal oxygen delivery catheter will be design with rubberized /plastic catheter with a single inlet and multiple (6-10) outlets for oxygen delivery. A multiportal suction catheter will be design with multiple (6-10) inlet and single outlet. Flexible body with easy storage and individual closure valve for each outlet. Material should be able to withstand moderate pressure of oxygen and partial vacuum. Adaptable for man-operated or machine operated suction system.

*4. Mechanical device for rapid IV fluid delivery*

*Need:* After massive blood loss, it is needed to push IV fluid in as hard as possible. Usually the flow is 5-7 ml per minute due to gravity which can be increased to 30-40 ml per min which can be life saving. This is normally done manually. There is a need to make the process automatic and quantitative. The devices usually used for this purposes are very costly and beyond the scope of wide use.

*Rationale & work plan:* A simple design based on mechanical principles will be made and relevant data produces to achieve the rate of fluid transport safely and efficiently. Specifications will be developed theoretically and through modeling.

*Specifications:* Mechanical device for rapid IV fluid delivery will be design with plastic or metallic body that shall interact with 540 ml standard plastic infusion bottle. This device should be detachable and reusable and preferably have multiple speed option and also constant speed of infusion.

*5. Development of technologies for stopping internal bleeding*

*Need*: Instant stoppage of bleeding is the single most factor that can save lives. A need exists to introduce new but simple devices exists because no drug has been found safe and effective till now. For making such devices, it is first essential to make testing devices because it is impossible and unethical to use animals for development purposes as hundreds will need to be sacrificed.

*Rationale:* Table top model will be needed to simulate bleeding into exterior for limbs while

closed space model will be required to simulate bleeding into cavities like abdomen and thorax. Tubes and fluid simulating arteries of various dimensions and blood respectively will be used in the model. Physical means like temperature change (that can coagulate the arteries) and high pressure (> 120 mm Hg) can stop bleeding temporarily so that natural coagulation can take place. Technology and devices based on temperature that are better / safer / more effective than what is currently practiced and those based on pressure effect that is innovative, need to be developed. The models will be standardized, vetted and used for experiments as outlined later.

*Specifications:* The catheters that mimic arteries of different dimensions (3 mm to 1 cm diameter) and made of plasticized rubber in density and character similar to human arteries will be modeled. Recyclable water (with density close to that of blood) in closed circulation orbit with a motor to provide pressure mimicking blood pressure in arteries will be the essential components of the models. Different sized perforations in the catheters, leaking fluid when connected to the motor system, will serve as models for bleeding arteries.

The other technologies will be based on a) steam and dry ice/liquid nitrogen to coagulate tubes by temperature changes or by b) air or water pressure to collapse the simulated arteries to stop leakage of water. This platform will be used to test and develop better technologies for stopping bleeding based on physical principles.

The experimental device made as item 8 will be used to test develop end perfect the device based on heat and pressure prior to animal testing at INMAS (Institute of Nuclear medicine and Allied Sciences).

## III. LITERATURE REVIEW

Tourniquet is used to stop bleeding at upper and lower limbs. A tourniquet can be defined as a compressing device used to control venous and arterial circulation to the upper or lower extremity for a period of time during war. Pressure is applied circumferentially upon the skin and underlying tissues of a limb; this pressure is transferred to the walls of vessels, causing them to become temporarily occluded. Non-inflatable or non-pneumatic tourniquets are usually made of rubber or elastic cloth. A pneumatic tourniquet uses an air inflated cuff to constrict blood flow. A regulating device on the tourniquet machine can control the amount of cuff pressure exerted on the limb [1].

The US Patent No. 6682547 B2 (2004) by James Allen McEwen refers to a Tourniquet cuff with identification apparatus. The cuff includes an inflatable bladder of a predetermined length greater than the circumference of a limb at a selected location and a cuff connector carried on the cuff and communicating pneumatically with the bladder for releasably connecting to a tourniquet instrument to establish a gas-tight passageway between the bladder and the instruments. The bladder may be formed by first joining an outer strip having varying thickness to an inner strip along the sides of the outer strip and then further joining the outer and inner strip together with gas-tight seals spaced apart by the predetermined length [2].

The US Patent No. 0310273 A1 (2012) by Patricia E. Thorpe describe Elastic tourniquet capable of infinitely adjustable compression. A tourniquet band is made of an elastic material and has a plush surface on one side and a series of hook fastener material patches on the reverse side. The woven structure includes a series of parallel elastic thread covered by a dense yet loosely coiled bundle of non-elastic threads. The non-elastic threads are oriented to form the plush surface while allowing the elastic core thread to elongate for applying pressure to a body part by elastic compression when the tourniquet is wrapped around the body part and secured by joining the hook material with the plush surface [3].

A limb scaffold is a compressing device used to support injured and bleeding mutilated limb during war. Oxygen is the most commonly used drug in emergency medicine and when used in the treatment of hypoxemia it undoubtedly saves life [4]. Oxygen catheters are medical devices that can be inserted in the body and deliver oxygen directly to the lungs. Suction catheter is essential when the patient is unable to clear the airway spontaneously and the secretion or aspirates are of detriment to the patient. Nasal and tracheal suction catheter is a flexible tube inserted through a narrow opening into cavity for removing fluid when all other methods are failed to remove secretions [5].

The mechanical device for rapid intravenous delivery is used to the infusion of liquid substances like blood, medicines or nutrients directly into a vein to correct electrolyte imbalance and also for dehydration. The intravenous route is the fasted way to transport fluids and medicines all over the body. Mainly the infusion pump was used for IV delivery, like peristaltic pump. Fluid is contained within a flexible tube fitted inside a circular pump casing. A rotor with a number of rollers, shoes, wipers or lobes attached to the external circumference of the rotor compresses the flexible tube. As the rotor turns, the part of the tube under compression is pinched closed (or "occludes") thus forcing the fluid to be pumped to move through the tube. Additionally, as the tube opens to its natural state after the passing of the cam ("restitution" or "resilience") fluid flow is induced to the pump. This process is called peristalsis and is used in many biological systems such as the gastrointestinal tract. Typically, there will be two or more rollers, or wipers, occluding the tube, trapping between them a body of fluid. The body of fluid is then transported, at ambient pressure, toward the pump outlet. Peristaltic pumps may run continuously, or they may be indexed through partial revolutions to deliver smaller amounts of fluid [6].

The US Patent No. 3609069 (1971) by Alfred Martinelli refers to Peristaltic pump for conveying liquids in chemical apparatus. The arrangement of this invention assures that the surface of plungers will not press directly upon the hoses. Further, the walls of the hoses follow steadily, rather than jerkily, any changes in the level of the plunger surfaces in cases where the plunger surfaces are arranged at different levels [7].

The US Patent No. 5980490 (1999) by Alexandre Tsoukalis describes a linear peristaltic pump.

This invention relates to linear peristaltic pump of known construction, in which first cam and a first cam follower in the form of an input valve, at least three intermediate cams and cam followers for pumping operation and a last cam and a last cam follower in the form of an output valve are used [8].

The US Patent No. 3756752 (1973) by Gustav H. Stenner refers to a peristaltic pump. This pump including a readily replaceable tube with nipples affixed to the ends and which fit and are anchored by sockets in the pump casing, and a rotor disk provided with a tube guide for guiding a replacement tube into operative position in the casing [9].

Cooling helmet, jacket and blanket are required to cool the body during heat stroke till the victim is able to reach the hospital. Heat stroke is common and death is possible when a soldier work in temperature over $50^{o}$ C.

The US Patent No. 5524293 (1996) by King Y. Kung refers to a cooling vest comprising an upper body cover with a pocket extending over a substantial part of the cover, and a flexible laminar vessel for cooling fluid arranged to fit and be supported in the pocket so as to extend and lie generally flat against the body of a wearer. A pocket may be provided in both a front and a rear body cover and a separate vessel in each pocket. The vessel may be formed of a number of separate fluid compartments. The compartments are filled with water [10].

The US Patent No. 3950789 (1976) by Stephan A. Konz and Jerrry R. Duncan relate to a personal cooling jacket which utilizes cold carbon dioxide gas to provide convection cooling. Cooling by convection is maximized, while cooling by conduction, although it occurs to some extent, is relatively less important [11].

## IV. METHODOLOGY

1. First step to apply the process design is identifying the product design specification. Product design specification is the product function, design requirement and design criteria will identify to solve the problem. Some of the criteria that will consider for the devices are performance, size and material selection.

2. The second stage is prelude design which will first simulate in fluid mechanics software (openFOAM and openFVM).

The openFOAM (Open Source Field Operation and Manipulation) C++ library is fluid mechanics software. The application of openFOAM divided into two categories, first is solvers, that are each designed to solve a specific problem in continuum mechanics and second is utilities, that are designed to perform tasks that involve data manipulation. One of the strength of openFOAM is that new solver and utilities can be created with some pre-requisite knowledge of the underlying method, physics and programming techniques involved. OpenFOAM is supplied with pre-and post-processing environments [12].

Standard solvers:

The $FOAM_SOLVERS directory in OpenFOAM is further subdivided into several directories by categories of continuum mechanics, e.g. incompressible flow, combustion, compressible flow, multiphase flow, conjugate heat transfer and solid body stress analysis.

Standard utilities:

The list of $FOAM_UTILITIES directory in OpenFOAM distribution is

Pre-processing

| | |
|---|---|
| applyBoundaryLayer | Apply a simplified boundary-layer model to the velocity and turbulence fields based on the 1/7th power-law |
| applyWallFunctionBoundaryConditions | Updates OpenFOAM RAS cases to use the new (v1.6) wall function framework |
| boxTurb | Makes a box of turbulence which conforms to a given energy spectrum and is divergence free |
| createExternalCoupledPatchGeometry | Application to generate the patch geometry (points and faces) for use with the externalCoupled boundary condition |
| dsmcInitialise | Initialise a case for dsmcFoam by reading the initialization dictionary system/dsmcInitialise |
| engineSwirl | Generates a swirling flow for engine calulations |
| faceAgglomerate | Agglomerate boundary faces for use with the view factor radiation model. Writes a map from the fine to the coarse grid. |
| foamUpgradeCyclics | Tool to upgrade mesh and fields for split cyclics |
| foamUpgradeFvSolution | Simple tool to upgrade the syntax of system/fvSolution::solvers |
| mapFields | Maps volume fields from one mesh to another, reading and interpolating all fields present in the time directory of both cases. Parallel and non-parallel cases are handled without the need to reconstruct them first |
| mdInitialise | Initialises fields for a molecular dynamics (MD) simulation |
| setFields | Set values on a selected set of cells/patchfaces through a dictionary |

| | |
|---|---|
| viewFactorsGen | Calculates view factors based on agglomerated faces (faceAgglomerat) for view factor radiation model. |
| wallFunctionTable | Generates a table suitable for use by tabulated wall functions |

Post-processing velocity fields

| | |
|---|---|
| Co | Calculates and writes the Courant number obtained from field phi as a volScalarField. |
| enstrophy | Calculates and writes the enstrophy of the velocity field U |
| flowType | Calculates and writes the flowType of velocity field U |
| Lambda2 | Calculates and writes the second largest eigenvalue of the sum of the square of the symmetrical and anti-symmetrical parts of the velocity gradient tensor |
| Mach | Calculates and optionally writes the local Mach number from the velocity field U at each time |
| Pe | Calculates and writes the Pe number as a surfaceScalar-Field obtained from field phi |
| Q | Calculates and writes the second invariant of the velocity gradient tensor |
| streamFunction | Calculates and writes the stream function of velocity field U at each time |
| uprime | Calculates and writes the scalar field of uprime ( $\overline{2 \quad 3}$ ) |
| vorticity | Calculates and writes the vorticity of velocity field U |

The openFVM (Finite Volume Method) is a three dimensional CFD (Computational fluid Dynamics) unstructured finite volume non-isothermal incompressible two phase flow solver. The new version of this software is able to solve the material properties e.g., Density of fluid, Viscosity of fluid, Specific heat of fluid, Thermal conductivity of fluid, Compressibility of fluid can be simulate in openFVM.

3. The third stage is to sketch of design idea that will suitable with the product design specification and the simulation in AutoCAD software. There will be some sketching of these devices and after evaluation 1 will has been choose.

The AutoCAD software is 2D and 3D computer aided designing and drafting. Generating design

ideas in almost any from imaginable with AutoCAD design features. Push/pull faces, edges and vertexes to model complex shapes, add smooth surface and more. AutoCAD can analyze the continuity, curvature and draft of 3D solids and surfaces. In AutoCAD any shape can be designed e.g. line, polygon, rectangle, circle, ellipse.

4. The final stage is final design. In the final design process, all the detail drawings and final specifications will be fabricate with appropriate material and test in INMAS (Institute of Nuclear medicine and Allied Sciences), DRDO (Defence Research & Development Organization).

**REFERENCES**

[1] "Tourniquet guide" VBM India Corporation.

[2] "Tourniquet cuff with identification apparatus" United States Patent, McEwen et al., (2004).

[3] "Elastic tourniquet capable of infinitely adjustable compression" United States Patent, Thrope, (2012).

[4] Kane B, Decalmer S, O"Driscoll B R, "Emergency oxygen therapy: from guideline to implementation" ERS vol 9 (2013).

[5] Nasal and tracheal suction (2004).

[6] "Peristaltic pump" Wikipedia, the free encyclopedia.

[7] "Peristaltic pump for conveying liquids in chemical apparatus" United States Patent, (1971).

[8] "Linear peristaltic pump" United States Patent, Tsoukalis, (1999).

[9] "Peristaltic pump" United States Patent, Stenner, (1973).

[10] "Cooling vest" United States Patent, Kung, (1996).

[11] "Dry ice cooling jacket" United State Patent, Konz et al., (1976).

[12] "OpenFOAM, The Open Source CFD Toolbox. User guide, (2014).